K123942
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4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 324 5412
www.stryker.com

stryker
Instruments

APR 0 3 2013

510(k) Summary

1. Contact Details

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-389-5412

Christina McKee
Christina.McKee@Stryker.com

December 7, 2012

2. Device Name

Trade Name: Stryker® iVAS Balloon Catheter

Common Name: Inflatable Bone Tamp

Classification Name:
Arthroscope
Cement, Bone, Vertebroplasty

Regulation Number:
§888.1100
§888.3027

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K113477	HRX NDN	Stryker® iVAS Balloon Catheter	Stryker Instruments
K103807	HRX NDN	Stryker® iVAS Balloon Catheter	Stryker Instruments
K093419	HRX NDN	Stryker® iVAS Balloon Catheter	Stryker Instruments

K110998	HRX NDN	AFFIRM™ VCF System	Algea Therapies
K041454	HRX	Xpander Inflatable Bone Tamps	Kyphon Inc.

4. Device Description

The Stryker® iVAS balloon catheter is a bone tamp with an inflatable component (balloon) at the distal end. The balloon is inflated to create a void within the vertebral body.

5. Intended Use/Indications for use

The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation with Cortoss ® and cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty. Vertebral Compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma.

6. Substantial Equivalence Comparison

Stryker® iVAS Balloon Catheter	**Stryker® iVAS Balloon Catheter (Predicates)**	**AFFIRM™ VCF System**	**Xpander Inflatable Bone Tamps**	**Comparison**
Indications for Use				
The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation with Cortoss ® and cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral	The Stryker iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements and Cortoss® Bone Augmentation Material indicated for	The AFFIRM™ VCF System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. Vertebral Compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system	KyphX® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KyphX® HV-RTM Bone Cement), hand,	All products are indicated for the reduction of fractures and/or creation of a void in cancellous bone. Kyphon Xpander is indicated for kyphoplasty while Stryker® iVAS's indications call out percutaneous vertebral augmentation. Percutaneous vertebral augmentation is a generic term and includes

augmentation procedures, such as kyphoplasty. Vertebral Compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma.	use during percutaneous vertebral augmentation procedures, such as kyphoplasty.	is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	tibia, radius and calcaneus.	Kyphoplasty which is a type of percutaneous vertebral augmentation. The Stryker® iVAS Inflatable Vertebral Augmentation System and the AFFIRM™ VCF System indications for use include a statement that Vertebral Compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma.

7. Non-clinical Testing

The Stryker® iVAS balloon catheter meets the specification and performance characteristics and are substantially equivalent to the predicate devices. Testing was completed in the previous 510k submissions (K113477, K103807 and K093419) and is reflective of the substantial equivalence to the predicate devices. Bench testing was performed for the removal of the contraindication "Fractures in which more than 68% of vertebral height is lost."

8. Clinical Testing

No clinical testing was deemed necessary for this submission.

9. Conclusions

The Stryker® iVAS balloon catheter is substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the Stryker® iVAS Balloon Catheter, the AFFIRM™ VCF System and the Kyphx Xpander Inflatable Bone Tamp. The products have the same fundamental scientific technology, basic design, functional characteristics and the same clinical applications. The Stryker® iVAS balloon catheter does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker® iVAS balloon catheter is equivalent to the existing predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporation
% Ms. Christina McKee
Regulatory Affairs Associate Analyst
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Letter dated: April 3, 2013

Re: K123942
Trade Name: Stryker Inflatable Vertebral Augmentation System (iVAS)
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: February 27, 2013
Received: February 28, 2013

Dear Ms. McKee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): _____

Device Name: Stryker Inflatable Vertebral Augmentation System (iVAS)

Indications for Use

The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation with Cortoss ® and cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty. Vertebral Compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma.

Prescription Use ____X____ and/or Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123942